

Serial Number 10/685,266  
Office Action mailed June 14, 2006  
Amendment filed September 14, 2006

## Remarks

Applicants have amended claim 18. Support for the amendment can be found throughout the specification, for example at page 16, lines 9 – 11, page 18, line 14, and page 19, line 5. Accordingly, no new matter is introduced by the virtue of the amendment and its entry is respectfully requested.

The Examiner objected to claim 18 because of the grammar. In light of the amendments to claim 18, Applicants respectfully submit that the objection be withdrawn.

The Examiner objected to the title. Applicants have amended the title to specifically indicate that the present application is directed to methods of treating onychomycosis. No new matter is introduced by this amendment and its entry is respectfully requested. Accordingly, Applicants respectfully request that the objection to the title be withdrawn.

The Examiner objected to the specification stating it had an imperfect priority claim. Applicants have amended the specification to perfect the priority data. No new matter is introduced by this amendment and its entry is respectfully requested. Accordingly, Applicants respectfully request that the objection to the specification be withdrawn.

Claims 18-20 were rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 5,620,994 (“994”).

Applicants respectfully submit that the rejection be withdrawn for the following reasons.

Applicants have amended claim 18 to a preferred embodiment, namely treating onychomycosis by applying the antifungal agent topically on the nail of a subject having onychomycosis.

Serial Number 10/685,266  
Office Action mailed June 14, 2006  
Amendment filed September 14, 2006

Onychomycosis is a fungal infection of nail that has proven difficult to treat. The application teaches and claims topically applying at the site of onychomycosis infection, i.e., the nail, an effective amount of an azolylamine derivative. Treatment of onychomycosis significantly differs from the general treatment of mycoses claimed in '994. Onychomycosis is a condition that specifically affects the nail plate. It has been generally the rule, as discussed in the present specification (see, e.g. p. 4, lines 9-13), that onychomycosis is particularly difficult or even impossible to treat using topical administration of any agent. It is well known that anti-fungal agents typically do not permeate the nail effectively enough to attack the fungus. Further, agents are easily removed from the top of the nail. The present invention shows the unexpected ability of an azolylamine derivative to penetrate nail and be retained by the nail, and thus be able to cure onychomycosis of the nail bed by topical application directly on the nail rather than using systemic application. Accordingly, the use of the compound in topical application to treat onychomycosis has a clear and unexpected superiority.

Accordingly, in light of the amendments and the discussion above, Applicants submit that the rejection be withdrawn.

Claims 18 – 20 were also rejected under 35 U.S.C. 102(f) and (g) as unpatentable over U.S. Patent No. 5,620,994.

Claims 18 – 20 were rejected under 35 U.S.C. § 102 (b) as anticipated by either U.S. Patent No. 5,620,994 or U.S. Patent No. 5,716,969.

Applicants respectfully submit that the rejections be withdrawn for the reasons discussed in detail, *supra*. The present invention is directed to a method for treating onychomycosis.

Serial Number 10/685,266  
Office Action mailed June 14, 2006  
Amendment filed September 14, 2006

Applicants submit that neither '994 nor '969 teach a specific method for treating onychomycosis.

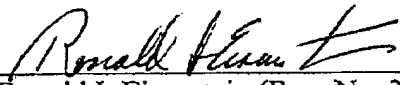
Onychomycosis is difficult to treat sub-class of mycoses. The condition is particularly difficult to treat in general, and has been almost impossible to treat using topical application of antifungals. The present claims overcome this difficulty. Accordingly, the present invention would not have been anticipated or obvious. Accordingly, the present claims are novel and the rejections should be withdrawn.

Furthermore, Applicants note that the present application and the '994 are commonly owned.

In view of the foregoing, Applicants respectfully submit that all claims are in condition for allowance. Early and favorable action is requested.

Respectfully submitted,

Date: 9/14/06

  
Ronald I. Eisenstein (Reg. No. 30,628)  
Leena H. Karttunen (L0207)  
NIXON PEABODY LLP  
100 Summer Street  
Boston, MA 02110  
(617) 345-6054/1367 (phone)  
(617) 345-1300 (fax)

**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE  
UNITED STATES PATENT AND TRADEMARK OFFICE**

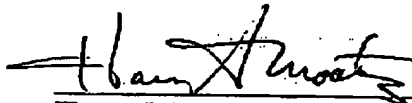
RECEIVED  
CENTRAL FAX CENTER  
SEP 14 2006

**LIMITED RECOGNITION UNDER 37 CFR § 11.9(b)**

Leena H. Karttunen is hereby given limited recognition under 37 CFR §11.9(b) as an employee of Nixon Peabody LLP, to prepare and prosecute patent applications wherein the patent applicant is the client of Nixon Peabody LLP and an attorney or agent of record in the applications is a registered practitioner who is a member of Nixon Peabody LLP. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Leena H. Karttunen ceases to lawfully reside in the United States, (ii) Leena H. Karttunen's employment with Nixon Peabody LLP ceases or is terminated, or (iii) Leena H. Karttunen ceases to remain or reside in the United States on an H-1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

Limited Recognition No. L0207  
Expires: February 11, 2007



**Harry I. Moatz**  
Director of Enrollment and Discipline